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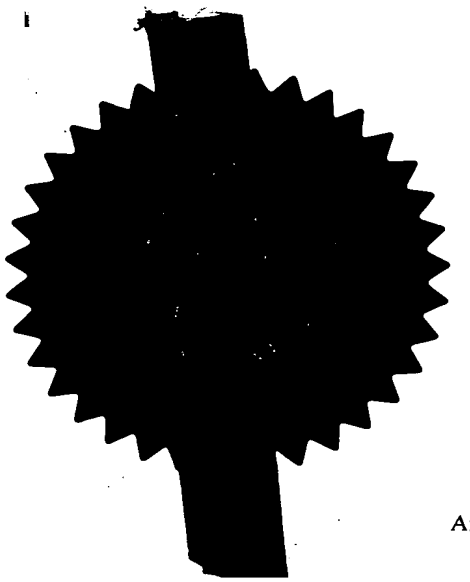

Signed Andrea Cooney

Dated 27 JAN 2000

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24 APR 1999

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1. Your reference CGR/PG3693

2. Patent application number *(The Patent Office will fill in this part)* 9909354.4

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GLAXO GROUP LTD
GLAXO WELLCOME HOUSE
BERKELEY AVENUE
GREENFORD
MIDDLESEX UB6 ONN UNITED KINGDOM

Patents ADP number *(if you know it)* 07358700 2

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

MEDICAMENT CARRIER

5. Name of your agent *(if you have one)*

DR CHRISTOPHER G PIKE

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

PIKE & CO.
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Patents ADP number *(if you know it)* 07497922001

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Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

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Number of earlier application	Date of filing *(day / month / year)*

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a) any applicant named in part 3 is not an inventor, or
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Claim(s)	3
Abstract	1
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Priority documents	
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Request for preliminary examination and search *(Patents Form 9/77)*	
Request for substantive examination *(Patents Form 10/77)*	
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11. I/We request the grant of a patent on the basis of this application.

Signature [signature] Date 23 APRIL 99

DR CG PIKE - AGENT FOR THE APPLICANT

12. Name and daytime telephone number of person to contact in the United Kingdom DR C G PIKE 01628 471869

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Medicament Carrier

The present invention relates to a medicament carrier for incorporation into an inhalation device to enable administration of medicament to a patient.

Inhalation devices are known for use with blister packs in which the medicament is held in powder form in the blisters thereof. Such packs are typically comprised of two separate entities, one of which is suitably formed to define the medicament pocket and the other is hermetically sealed to the first to form the medicament carrier. It is an object of the present invention to provide a medicament carrier wherein the carrier comprises a single elongate strip thus providing significant advantages over the prior art in that the strip is straightforward to manufacture, providing both ease of use and reduction in manufacturing costs.

Known blister packs generally include a puncturing member, which punctures each blister in turn thus enabling the medicament to be inhaled therefrom. Generally release of the medicament dose is by puncture or rupture of the second entity. Such packs suffer from the disadvantage that they may be difficult to use, particularly as the dose releasing means may comprise one or more elongate members, such as cords or tapes, which are separately attached to films used to seal the medicament pockets. The present invention provides advantages over such packs in that it is especially useful for the elderly and infirm since the free end of the strip is readily identifiable and simple to grasp, without the added complication of numerous cords or tapes which act as a separate release mechanism.

A further object of the present invention is to provide a medicament carrier for use in combination with an inhalation device, wherein the free end of the strip is peeled back automatically by virtue of a releasing means incorporated into the inhalation device, hence avoiding the need to grasp the strip manually. Such a feature further enhances the ease of use of the inhalation device since minimum force is required by the user to peel back the medicament pouch.

It is also an object of the present invention to provide a medicament carrier for use in combination with an inhalation device, wherein the design of the inhalation device has the potential, if desired, to handle a medicament carrier having a large number

of discrete unit doses without the device becoming unacceptably large. The present invention is particularly suitable for such use, as will be shown in embodiments, because the individual medicament containers have the ability to lie flat against the elongate strip thus forming a compact series of medicament containers.

A further advantage provided by the present invention is that the use of the flat medicament container allows air to pass over the whole container surface when opened thereby improving drug removal.

According to one aspect of the invention there is provided a medicament carrier comprising an elongate strip having a first portion and a second portion; a fold between said first portion and said second portion such that the first portion contacts the second portion; and a seal between the first portion and the second portion, wherein said seal and the fold form the edges of a pouch for containment of medicament.

In another aspect of the invention there is provided a medicament carrier comprising at least one further seal forming at least one further pouch for containment of medicament.

In another aspect of the invention there is provided a medicament carrier, wherein the ends of the elongate strip form a pair of pull release tabs.

Preferably, each of the pull release tabs is shaped for ease of grip.

Preferably, each of the pull release tabs has a looped end enabling them to be connected to a trigger mechanism incorporated within an inhalation device or for receipt of finger in manual release.

Preferably, each of the pull release tabs has at least one perforation allowing then to be easily grasped by the user or otherwise allowing them to be connected to a trigger mechanism incorporated within an inhalation device.

In another aspect of the invention there is provided a medicament carrier in multi-dose form comprising a series arrangement of a plurality of medicament carriers as described above.

Preferably, each of said plurality of medicament carriers is connected together.

More preferably, each of said plurality of medicament carriers is formable from the same elongate strip.

Preferably, the elongate strip has a point of weakness between each medicament carrier in said series arrangement, thereby enabling separation of individual medicament carriers from the strip.

Preferably, each pouch is foldable to lie flat alongside the elongate strip.

Preferably, the elongate strip is flexible to enable it to be formed, for example, into a spiral, helical or zig-zag shape for incorporation into a suitable inhalation device. More preferably, the elongate strip is made of an elastic material, for example, flexible foils or plastic materials.

Preferably, the seal is formable by a sealing method selected from the group consisting of heat, laser, radio frequency, adhesive, staple, stamp and ultrasonic sealing.

Preferably, the seal is peelable to enable peelable access to the pouch.

Preferably, the pouch comprises medicament in powder form.

In a further aspect of the invention there is provided an inhalation device comprising a housing in combination with a medicament carrier.

Preferably, the medicament carrier comprises a pair of pull release tabs and the pair of pull release tabs protrude from the housing of the inhalation device.

Preferably, the inhalation device comprises a release trigger and the pair of pull release tabs connect to the release trigger. More preferably, the release trigger is separable from the housing of the inhalation device.

According to another aspect of the invention there is provided a method of making a medicament carrier comprising forming a fold between a first portion and second portion of an elongate strip such that said first portion contacts said second portion; forming a seal between said first portion and said second portion wherein said seal and the fold form the edges of an open pouch for containment of medicament; filling said open pouch with medicament; and closing said open pouch by forming a further seal.

In another aspect of the invention there is provided a method of making a medicament carrier in multi-dose form comprising successive iterations of the method described hereinbefore to form a series arrangement of a plurality of medicament carriers.

According to another aspect of the invention there is provided a method of opening a medicament carrier as described herein comprising pulling the pair of pull release tabs in order to enable access to the pouch.

According to yet another aspect of the invention there is provided the use of a medicament carrier as described herein for dispensing medicament.

Preferably, the medicament is used in the treatment of respiratory disorders.

More preferably, the medicament is used in the treatment of asthma.

Preferably, the medicament is salbutamol or albuterol.

Preferred embodiments of the medicament carrier according to the present invention will now be described with reference to the accompanying drawings in which:

Fig. 1a is a perspective sideview of a first medicament carrier in accordance with the present invention in the closed and perpendicular configuration.

Fig. 1b is a perspective sideview of a first medicament carrier in accordance with the present invention in the open configuration.

Fig. 2a is a perspective sideview of a second medicament carrier in the closed flat configuration.

Fig. 2b is a perspective sideview of a second medicament container in the closed and perpendicular configuration.

Fig. 3 is a perspective sideview of a second medicament carrier in a multi-dose form.

Figure 1a shows a medicament carrier in the closed configuration comprising an elongate strip 10 having a first and second portion which are folded towards each other until contact is made. A pouch 20 is formed by sealing the two outside edges 12 and 14 of the elongate strip and the third edge 16 is sealed to provide a sealed medicament carrier after introduction of the medicament. The ends of the first and second portions then define a pair of pull release tabs 30 and 40 as shown. The contents of the pouch are 20 are released by pulling the pull release tabs 30 and 40 in an opposite direction, either manually or by an automatic releasing means so that the medicament carrier is then in the open configuration as shown in Figure 1b.

Figure 1b shows a medicament carrier in the open configuration wherein the pair of pull release tabs 30 and 40 have been sufficiently peeled in order to break the seal around the periphery of the pouch 20 thereby exposing the medicament contained therein.

Figure 2a shows a second medicament carrier wherein the pair of pull release tabs 130 and 140 both possess a perforation 150 enabling it to be connected to a trigger mechanism incorporated within an inhalation device, or for receipt of finger in manual release. The medicament pouch 120 lies flat along the elongate strip minimising the amount of space taken up by the medicament carrier when incorporated into an inhalation device.

Figure 2b shows the second medicament carrier of Figure 2a wherein the medicament pouch 120 is in the closed and perpendicular position ready for use. Exposure of the contents of the pouch 120 is achieved by pulling the pair of release tabs 130 and 140 in the direction shown as previously described in Figure 1a.

Figure 3 shows the second medicament carrier of Figure 2a in a multi-dose form. The multi-dose medicament carrier is formed from an elongate strip incorporating a number of first and second portions, each forming a medicament pouch 220. The individual medicament pouches are shown here in the closed flat configuration. Exposure of the pouch contents is achieved by pulling the pair of release tabs 230 and 240 in an opposite direction as previously described in Figure 1a.

Standard methods of filling and sealing the medicament container may be used and form another aspect of the present invention. Such methods include entering a hollow, or a number of hollow, pins into a reservoir of powder so that a defined quantity of powder is taken up into the or each pin. The pin, or number of pins, are then positioned above the individual medicament containers and the powder contained therein released by means of a piston. The medicament containers are subsequently sealed so that the powder is contained in a medicament container defined by the two portions of the elongate strip.

In another alternative method the medicament powder may be released from a powder reservoir housed within the inhalation device. For example, a bore is entered into the powder reservoir and the powder transferred through the bore by means of a fluted auger to a bore egress. The medicament powder is then released into a medicament pouch of the desired volume by means of a piston.

Suitable methods of sealing the medicament carrier include the use of adhesives, staples or stamps and welding methods selected from hot metal welding, radio frequency welding, laser welding and ultrasonic welding. Such sealing techniques may be used to form a suitable seal around the periphery of the medicament pouch which is capable of being peeled away by the patient or by a suitable trigger release mechanism in a controlled manner when in use.

Although not directly relevant to the present invention, it should be noted that medicaments suitable for administration by an inhalation device using the present invention are any drug particles suitable for delivery to the bronchial or alveolar region of the lung which have an aerodynamic diameter of less than 10 micrometers. Larger particles may be used if delivery to other portions of the respiratory tract is desired, such as the mouth or throat. Such medicaments may be selected from a wide range of powdered medicaments and may be in amorphous or crystalline form and may have been comminuted, e.g. ground, and, if necessary, classified and sieved, e.g. on an air jet sieve, to obtain a suitable size or may have been made by direct crystallisation to the desired size.

Appropriate medicaments may thus be selected from those suitable for inhalation, for example, analgesics, e.g. codene, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem; anti-allergics, e.g., cromoglycate, ketotifen or nedocromil; anti-infective e.g.,cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines and pentamidine; anti-histamines e.g., methapyrilene; anti-inflammatories e.g., beclomethasone dipropionate, fluticosone propionate, flunisolide, budesonide, rofleponide, mometasone furoate or triamcinolone acetonide; anti-tussives, e.g. noscapine; bronchodilators, e.g., albuterol, salmeterol, ephedrine, adrenaline, fenoterol, formoterol, isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol, reproterol, rimitrol, terbutaline, isoetharine, tulobuterol, or (-)-4-amino-3,5-dichloro-α-[[[6-2-(-pyridinyl)ethoxy]hexyl]methyl]benzenemethanol; diuretics, e.g. amiloride; anticholinergics, e.g., ipratopium, tiotropium, atropine or oxitropium; hormones, e.g., cortisone, hydrocortisone or prednisolone; xanthines, e.g., aminophylline, choline theophyllinate, lysine theophyllinate to theophylline; therapeutic proteins and peptides, e.g., insulin or glucagon.

It will be clear to a person skilled in the art that, where appropriate, the medicaments may be used in the form of salts (e.g. as alkaline metal or amine salts or as acid addition salts) or as esters (e.g. low alkyl esters) or as solvates (e.g. hydrates) to optimise the activity and/or stability of the medicaments.

Preferred medicaments are selected from albuterol, salmeterol, fluticasone propionate and becomethasone dipropionate or solvates thereof, e.g. . the sulphate of albuterol and xinafoate of salmeterol.

Medicaments can also be delivered in combinations. Preferred formulations containing combinations of active ingredients contain salbutamol (e.g., as the free base or the sulphate salt) or salmeterol (e.g. as in xinafoate salt) in combination with an anti-inflammatory steroid such as beclomethasone ester (e.g., the diproprionate) or fluticasone ester (e.g., the proprionate).

It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations and improvements thereto.

The application of which this description and claims form part may be used as a basis for priority in respect of any subsequent application. The claims of such subsequent application may be directed to any feature or combination of features described therein. They may take the form of product, method or use claims or may include, by way of example and without limitation, one or more of the following claims:

Claims

1. A medicament carrier comprising an elongate strip having a first portion and a second portion; a fold between said first portion and said second portion such that the first portion contacts the second portion; and a seal between the first portion and the second portion, wherein said seal and the fold form the edges of a pouch for containment of medicament.

2. A medicament carrier according to claim 1 comprising at least one further seal forming at least one further pouch for containment of medicament.

3. A medicament carrier according to either of claims 1 or 2, wherein the ends of the elongate strip form a pair of pull release tabs.

4. A medicament carrier according to claim 3, wherein each of the pull release tabs is shaped for ease of grip.

5. A medicament carrier according to either of claims 3 or 4, wherein each of the pull release tabs has a looped end.

6. A medicament carrier according to any of claims 3 to 5, wherein each of the pull release tabs has at least one perforation therein.

7. A medicament carrier in multi-dose form comprising a series arrangement of a plurality of medicament carriers according to any of claims 1 to 6.

8. A medicament carrier according to claim 7, wherein each of said plurality of medicament carriers is connected together.

9. A medicament carrier according to claim 8, wherein each of said plurality of medicament carriers is formable from the same elongate strip.

10. A medicament carrier according to claim 9, wherein said strip has a point of weakness between each medicament carrier in said series arrangement.

11. A medicament carrier according to any one of claims 7 to 10, wherein each pouch is foldable to lie flat alongside the elongate strip.

12. A medicament carrier according to any claims 1 to 11, wherein the elongate strip is flexible.

13. A medicament carrier according to any of claims 1 to 12, wherein the elongate strip is made of an elastic material.

14. A medicament carrier according to any one of claims 1 to 13, wherein the seal is formable by a sealing method selected from the group consisting of heat, laser, radio frequency, adhesive, staple, stamp and ultrasonic sealing.

15. A medicament carrier according to any one of claims 1 to 14, wherein the seal is peelable to enable peelable access to the pouch.

16. A medicament carrier according to any one of claims 1 to 15, wherein the pouch comprises medicament in powder form.

17. An inhalation device comprising a housing in combination with a medicament carrier as claimed in any one of claims 1 to 16.

18. An inhalation device according to claim 17, wherein the medicament carrier comprises a pair of pull release tabs and the pair of pull release tabs protrude from the housing of the inhalation device.

19. An inhalation device according to either of claim 17 or 18, wherein the inhalation device comprises a release trigger and the pair of pull release tabs connect to the release trigger.

20. An inhalation device according to claim 19, wherein the release trigger is separable from the housing of the inhalation device.

21. A method of making a medicament carrier comprising forming a fold between a first portion and second portion of an elongate strip such that said first portion contacts said second portion; forming a seal between said first portion and said second portion wherein said seal and the fold form the edges of an open pouch for containment of medicament; filling said open pouch with medicament; and closing said open pouch by forming a further seal.

22. A method of making a medicament carrier in multi-dose form comprising successive iterations of the method of claim 21 to form a series arrangement of a plurality of medicament carriers.

23. A method of opening a medicament carrier as claimed in claims 3 to 15 comprising pulling the pair of pull release tabs in order to enable access to the pouch.

24. Use of a medicament carrier, according to claim 16 for dispensing medicament.

25. Use of a carrier according to claim 24, wherein said medicament is used in the treatment of respiratory disorders.

26. Use of a carrier according to claim 25, wherein said medicament is used in the treatment of asthma.

27. Use of a carrier according to claim 26, wherein said medicament is salbutamol or albuterol.

28. A medicament carrier as substantially herein described with reference to the accompanying drawings.

29. An inhalation device as substantially herein described with reference to the accompanying drawings.

Abstract

There is provided a medicament carrier for use in combination with an inhalation device suitable for dispensing medicament, particularly for use in the treatment of respiratory disorders. The medicament carrier comprises an elongate strip having a first portion and a second portion; a fold between said first portion and said second portion such that the first portion contacts the second portion; and a seal between the first portion and the second portion, wherein said seal and the fold form the edges of a pouch for containment of medicament. A method of making the medicament carrier is also provided.

FIGURE 1a

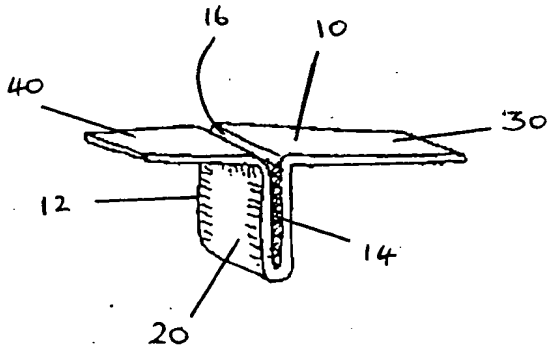

FIGURE 1b

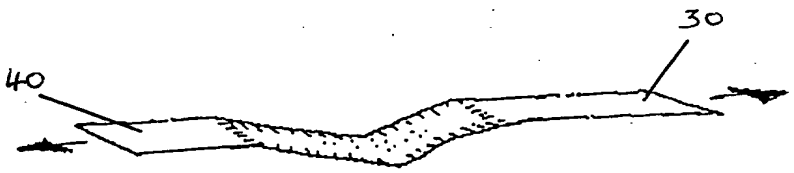

FIGURE 2a

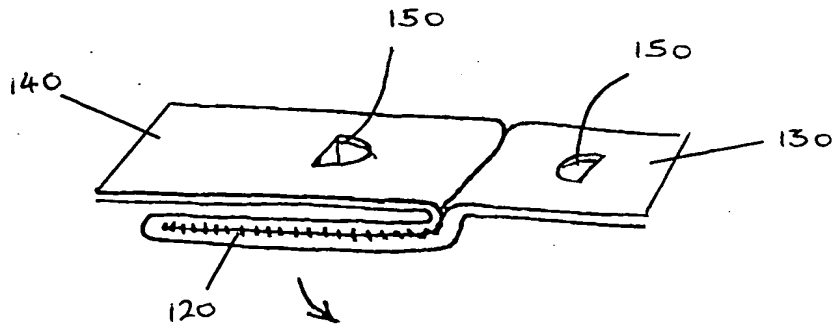

Figure 2b

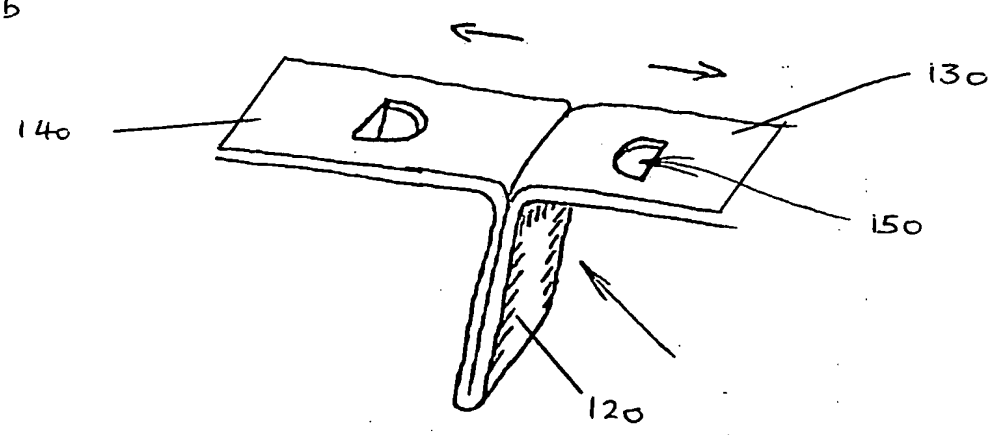

FIGURE 3